Background

Clothianidin is a neonicotinoid insecticide first registered in 2003 and currently used on a wide variety of use sites. Clothianidin's major risk concern is to nontarget terrestrial insects (that is, honey bees) though other risks have been identified to aquatic free-swimming and benthic invertebrates, birds, and mammals.

Clothianidin is both persistent and systemic. Acute toxicity studies to honey bees show that clothianidin is highly toxic on both a contact and an oral basis. Information from standard tests and field studies, as well as incident reports involving other neonicotinoids insecticides (e.g., imidacloprid) suggest the potential for long term toxic risk to honey bees and other beneficial insects. An incident in Germany already illustrated the toxicity of clothianidin to honeybees when allowed to drift off-site due to dust from abraded particles from treated seed during planting.

Current Issue

Although not specifically stated in the email it appears that this comment is in response to the re-review of a specific field study conducted as part of a recent new use risk assessment. What follows is a brief summary of the history of that study.

In 2007, EFED reviewed the study entitled, "An Investigation of the Potential Long-Term Impact of Clothianidin Seed Treated Canola on Honey Bees, *Apis mellifera* L." (MRID 46907801), and classified it as "Acceptable" satisfying the guideline 850.3040 field study for pollinators. However, since the initial review a number of deficiencies were noted in the study review, including cross contamination between treated and non-treated (control) portions of the study and inadequate separation between treated and control portions of the study.

On November 2, 2010 EFED completed a new use assessment for clothianidin for Seed Treatment on Mustard Seed (Oilseed and Condiment) and Cotton. At this time EFED rev-reviewed the original honey bee field study in light of current understanding of issues associated with field studies that highlight challenges in field study design and in response to concerns raised by stakeholders.

Based on this current understanding and the deficiencies noted above the initial re-review of this study yielded a reclassification to invalid and a reclassification memo was sent to the Registration Division.

However, subsequent to that review EFED reconsidered whether there was any useful information in the study that could be used in the risk assessment for clothidianin. Based on the new review, it was decided that the study contained useful information on the overwintering success of bees; therefore the study was reclassification "supplemental" rather than "invalid".

In response to this re-review EFED submitted a revised reclassification memo and an

updated risk assessment to RD on December 2, 2010 along with a memorandum documenting the impact of the changes on the risk assessment. In that memo EFED noted the results of the overwintering part of the study showed that the majority of the hives, including those exposed to clothianidin during the previous season, survived the overwintering period. However, the review also indicates that this study can only be used to provide a qualitative description of hive survival following the exposure to clothianidin at the levels that were described in the study. EFED is in the process of revising the data evaluation record (DER) for this study.

Also in the December 2, 2010 update EFED noted that another field study is needed to evaluate the effects of clothianidin on bees through contaminated pollen and nectar and thus exposure through contaminated pollen and nectar and that potential toxic effects remain an uncertainty for pollinators.

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